

# Comparison of Liner Assisted Suspensions in Transtibial Prosthetics: A Pilot Study

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# Amputation and Volume loss



- **Persons with amputation experience volume loss**
  - ✦ **Increased pistoning of limb inside the socket**
    - Pistoning is vertical displacement
  - ✦ **Increased pressure and shear stresses at the bony prominences**
  - ✦ **Pressure and shear**
    - Wounds
    - Pain
    - Infection
    - Re-amputation
    - Decreased activity

(Highsmith 2007)

# Importance?



- How do we accommodate for volume loss?
  - Socks
  - Socket modification
  - Suspension system
- How do we know what is appropriate?



# Outcome Measures



- Quantify the difference between groups due to differing interventions
  - Quantitative and qualitative
  - Surveys, questionnaires, timed tests
  - Justification for device types
  - Helps formulate prosthetic prescription recommendations

# Test Conditions

- **Elevated Vacuum:**

LimbLogic<sup>®</sup> VS

Pump turned ON

- Maintains a specified level of vacuum;  
can be changed

- **Suction:**

LimbLogic<sup>®</sup> VS

Pump turned OFF

- One way expulsion valve



# Test Conditions



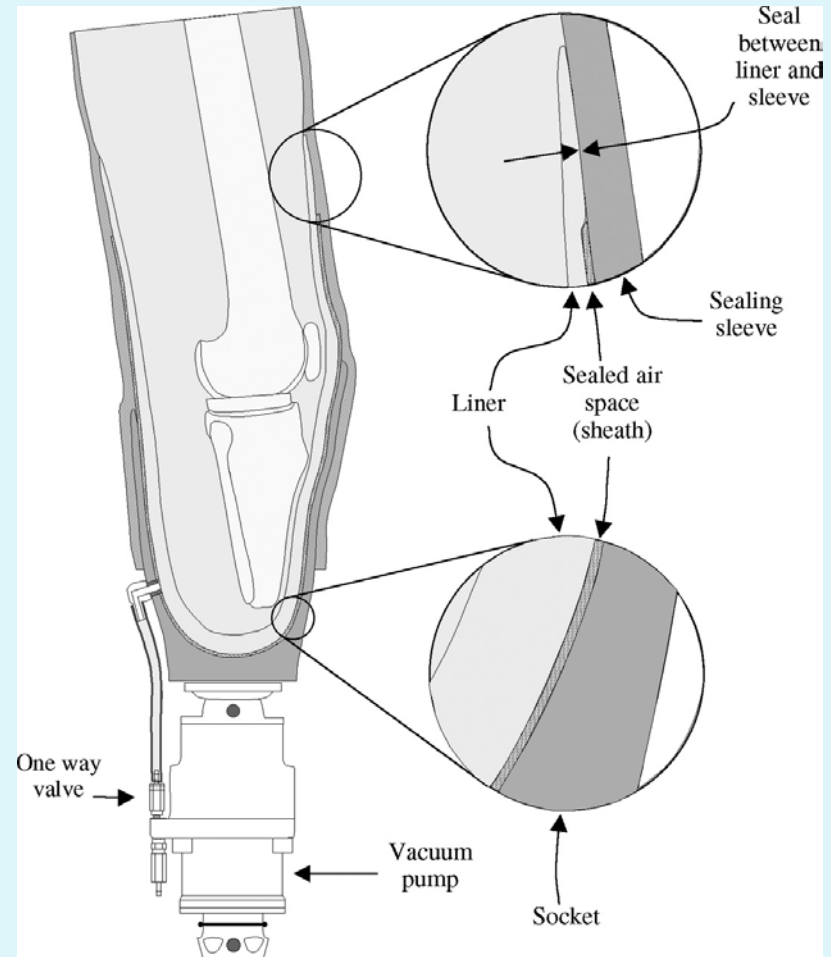
- **Dynamic Vacuum Liner (DVL)**

- Elevated vacuum



# What is Vacuum?

- Vacuum suspension
  - Created in 1999 (Board 2001)
  - Removes air molecules from inside of the socket
  - Negative pressure
    - ✦ Holds the socket on the limb
    - ✦ Increases contact of liner to socket walls (Street 2007)



Street 2007

# Donning the Socket



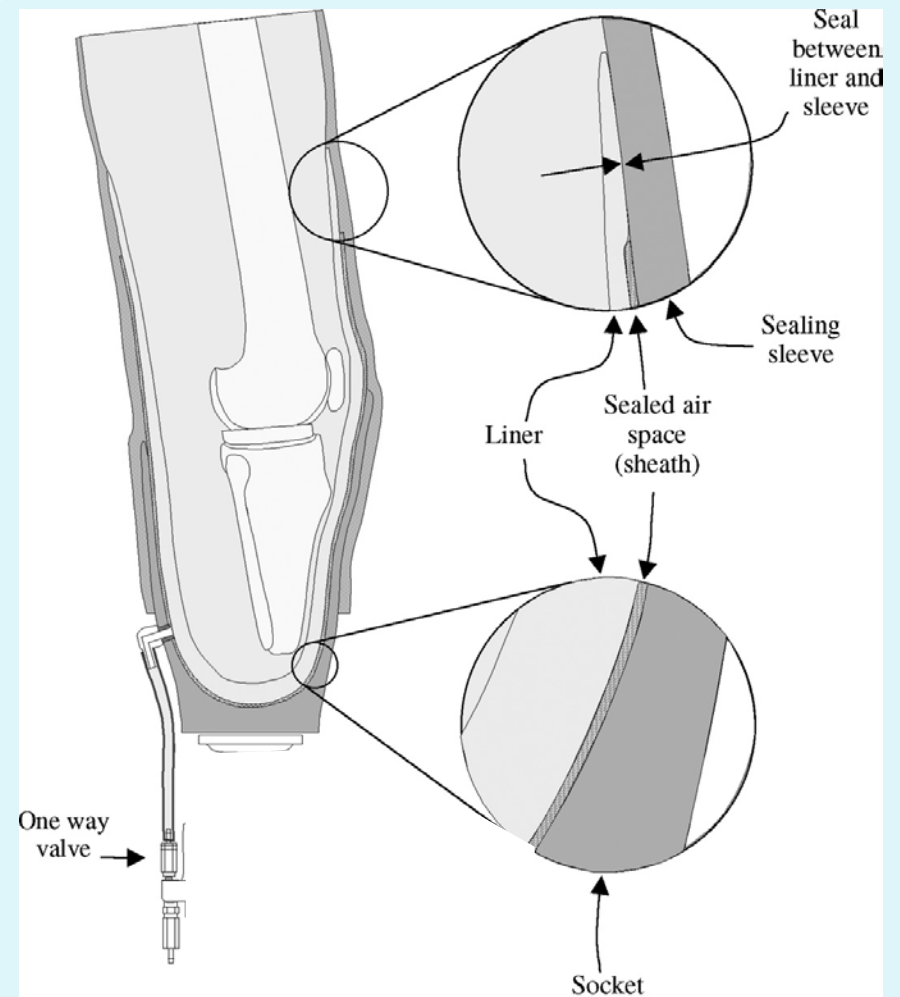


# Forms of Vacuum



- **Suction**

- Air is expelled during weight bearing through one way expulsion valve



# Forms of Elevated Vacuum

- LimbLogic<sup>®</sup> VS



LimbLogic<sup>®</sup> VS  
from  
Ohio Willow Wood<sup>®</sup>

- DVL

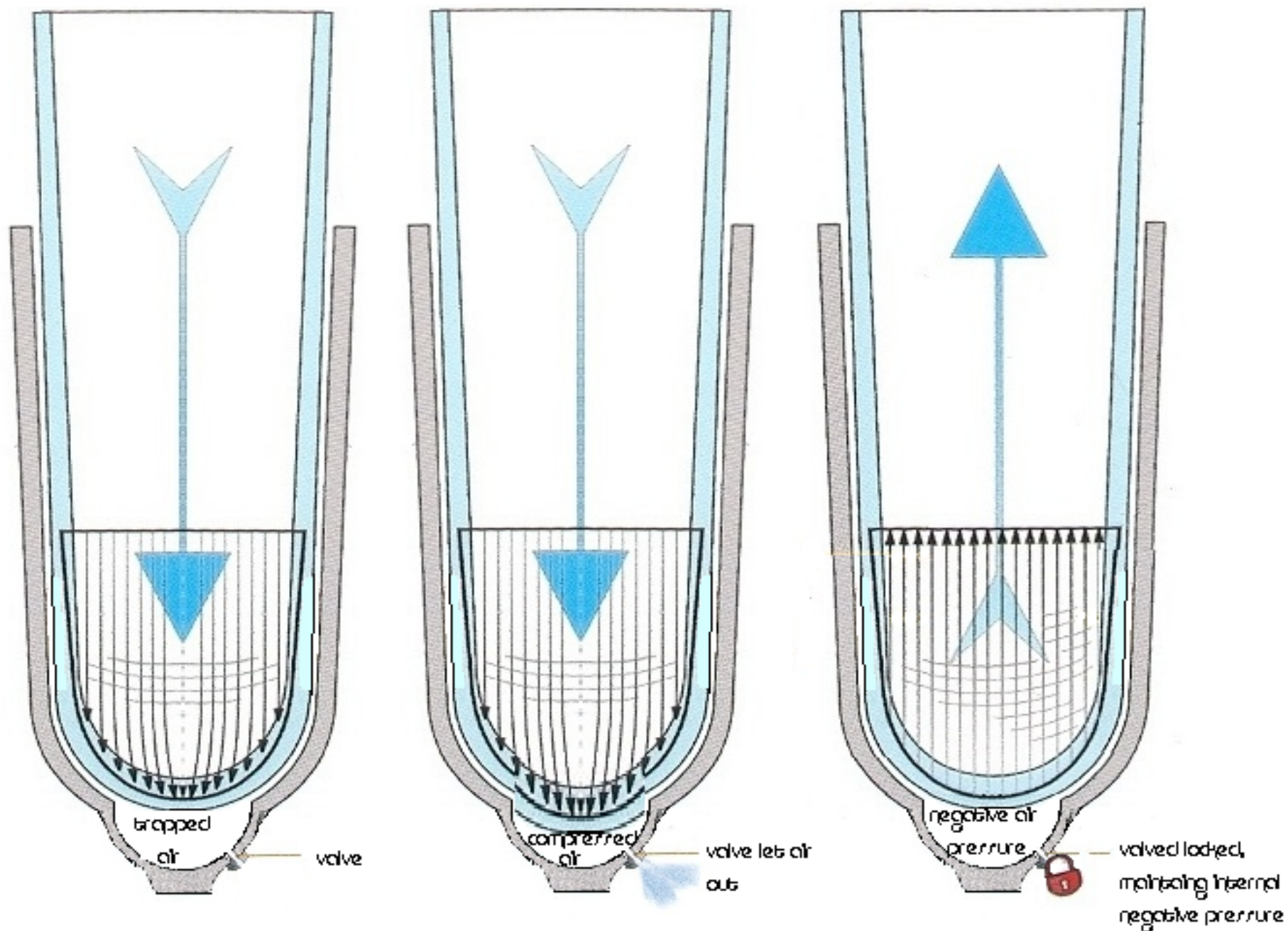


Dynamic Vacuum Liner  
(DVL)

# Dynamic Vacuum Liner



- The DVL consists of custom silicone liner and socket
- Vacuum created through the custom silicone liner and unique fabrication of the distal end of the socket



# How do pressures affect the limb?



- **Positive pressure pushes fluid up out of the RL**
  - Causes a decrease in RL volume
- **Negative pressure draws fluid into the RL**
  - Keeps RL volume stable

# Research on Vacuum Suspension



- **Elevated vacuum suspension**

- Promotes wound healing
- Decreased volume loss

- Decreased RL volume loss
- Decreased positive pressures



= may promote  
increased activity

(Brunelli 2009, Beil 2007)

# Research of Vacuum Systems



- Comparison of RL volume in two vacuum systems
  - Suction : **Decreased** 6.5%
  - Elevated Vacuum: **Increased** 3.7%
- Pressure Changes
  - Vacuum sockets
    - ✦ 27% **Increased** negative pressure during swing
    - ✦ 7% **Decreased** positive pressure during stance

(Board 2001, Goswami 2003, Beil 2002)

# Outcome Measures



## **Trinity Amputation and Prosthesis Experience Scales (TAPES)**

- Measures perceived restriction and satisfaction levels
- Subscales:
  - Athletic Activity Restriction
  - Functional Restriction
  - Weight Satisfaction
  - Functional Satisfaction
- Can be used to measure quality of life in rehab and give insight into nature of disability
- Only some of the subscales were applicable to study

(Gallagher 2004, Deans 2008)



# Outcome Measures



## **Prosthesis Evaluation Questionnaire (PEQ)**

- Measures perceived quality of life and satisfaction level
- Subscales:
  - Utility
  - Residual limb health
  - Frustration
- Validated survey; used in several studies

(Legro 1998, Coleman 2004, Van de Weg 2005)

# Outcome Measures



## **StepWatch™ Activity Monitor (SAM)**

- Microprocessor-controlled step counter
- Outcomes:
  - Average steps/day
  - Peak activity index
- Found to be more accurate than self-reported activity

(Coleman 2004, Stepien 2007)



# Outcome Measures



## **Modified Emory Functional Ambulation Profile (mEFAP)**

- 4 timed tasks
  - Walking 5-meters on a hard surface
  - Walking 5-meters on a carpeted surface
  - Timed Up and Go Test (TUGT)
  - Ascending and descending 5 steps
- Measures time elapsed to traverse common environmental terrains
  - Only been conducted on persons with stroke
  - With or without the use of an assistive device



# Aims



- To identify trends and distinguish characteristics that may **indicate or contraindicate** people with unilateral transtibial amputations for specific liner assisted suspension systems
- To determine the most **appropriate outcome measures** for future study
- To **calculate effect size estimates** which can be used to adequately power larger studies

# Methods



- **Protocol**
  - 5 two week phases
  - Multiple baseline study design
  - Subjects randomly assigned to 2 of 3 test conditions
  - Outcome measures:
    - ✦ mEFAP
    - ✦ TAPES/PEQ
    - ✦ SAM
    - ✦ Self-reported activity log
    - ✦ Knee ROM

# Phases



# Methods



- **Initial Appointments**
  - Informed consent
  - Clinical and prosthetic history taken
  - Casted/Scanned for test condition socket
  - Fabricated custom test condition socket
  - Fittings and dynamic alignments with licensed and certified prosthetist

# Subject recruitment



- **Inclusion Criteria**
  - Unilateral, transtibial amputation
  - Seal-in or locking liner suspension
  - At least 1 year post amputation
  - < 300lbs.
  - IRB approval



# Subjects



Subject	Age	Side of Amp	Male/Female	Time since Amp
1*	45	Left	Female	6
2*	38	Left	Male	31
3**	43	Left	Female	2
4	50	Left	Female	6
5	61	Right	Male	2

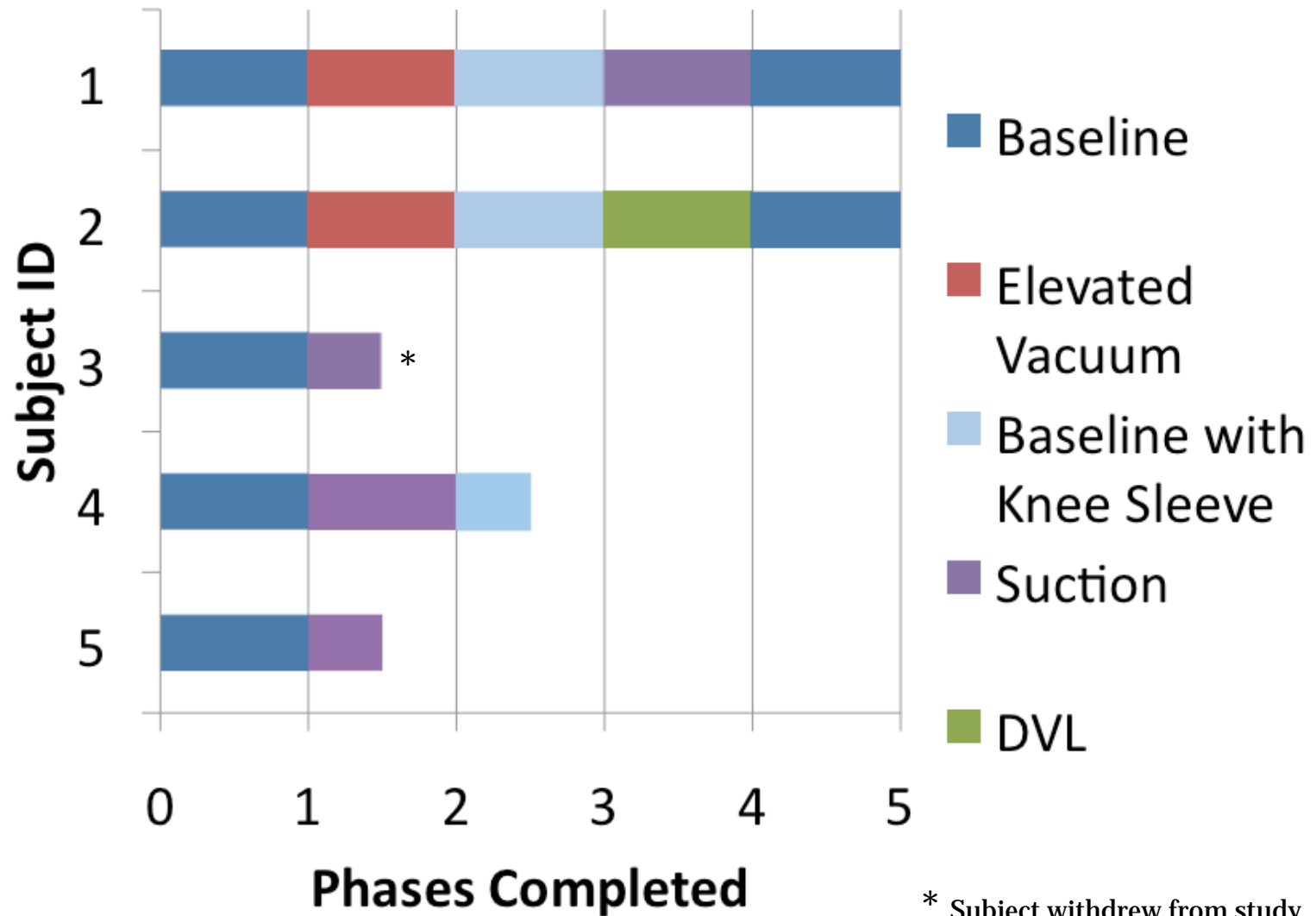
## Average

- Age – 47.4 yrs
- Time Since Amputation – 9.4 yrs

\*Completed Protocol

\*\*Subject discontinued study

## Study Progression - April 2010



# Test Conditions

- **Elevated Vacuum:**  
LimbLogic<sup>®</sup> VS  
Pump turned ON
- **Suction:**  
LimbLogic<sup>®</sup> VS  
Pump turned OFF
- **Dynamic Vacuum Liner (DVL)**



# Subject 1



- 45 yo female
- 6 yrs since amputation
- Current prosthesis 6 yrs old
- Poor socket fit
- Locking pin system
- No insurance coverage
  - Limited access to prosthetic componentry and supplies
- Experienced wearer

# Subject 2



- 38 yo male
- 31 yrs since amputation
- Current prosthesis 1-2 years old
- Locking pin system
- Has insurance and good relationship with prosthetist
  - Regular prosthetic maintenance and adjustments
  - Experience with several types of suspension
- Very experienced wearer and can accommodate to different components and alignment

# Self-Reported Activity Log



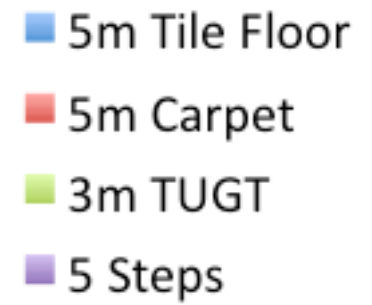
- **Subject 1**
  - Pinched nerve in back
  - Nerve pain at distal end of RL
  - More active with study prosthesis
- **Subject 2**
  - Plays racquetball
    - ✦ Didn't wear study prosthesis
  - Didn't work during phase 5

# Phase Designations

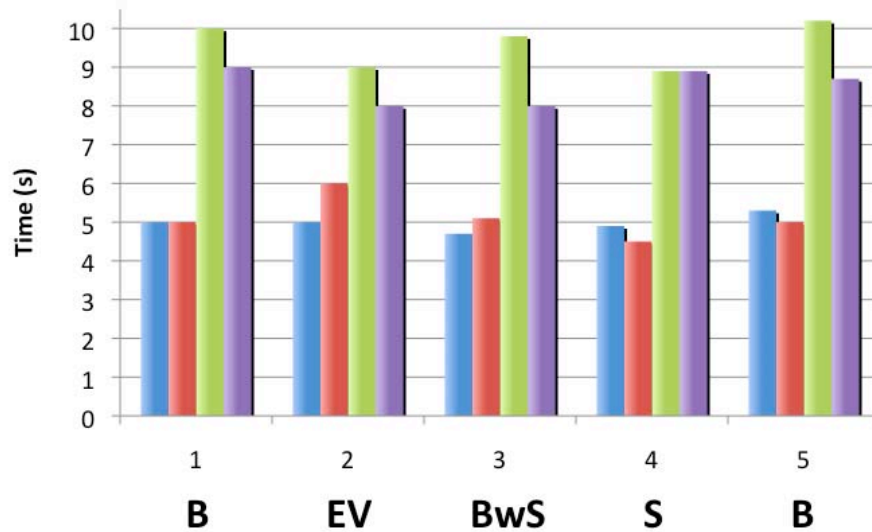


Phase	Subject 1		Subject 2	
1	<b>B</b>	Baseline	<b>B</b>	Baseline
2	<b>EV</b>	Elevated Vacuum	<b>EV</b>	Elevated Vacuum
3	<b>BwS</b>	Baseline with Sleeve	<b>BwS</b>	Baseline with Sleeve
4	<b>S</b>	Suction	<b>DVL</b>	Dynamic Vacuum Liner
5	<b>B</b>	Baseline	<b>B</b>	Baseline

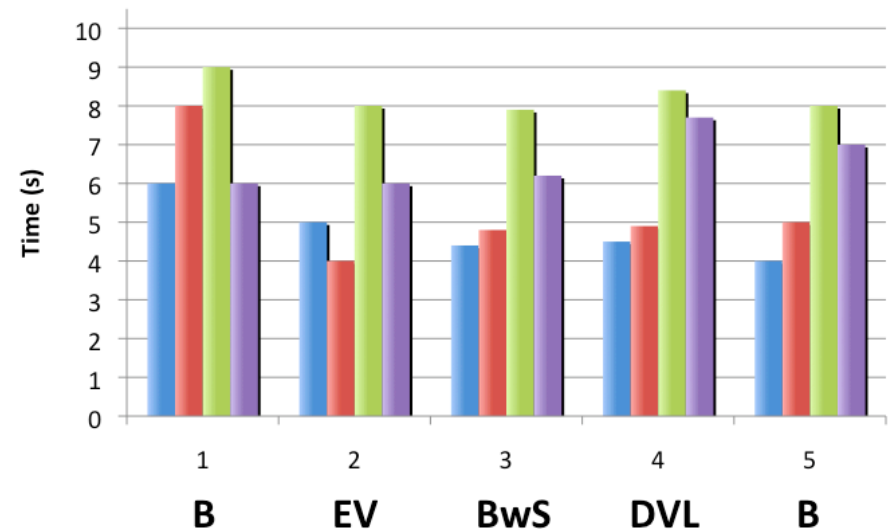
# mEFAP Results



Subject 1



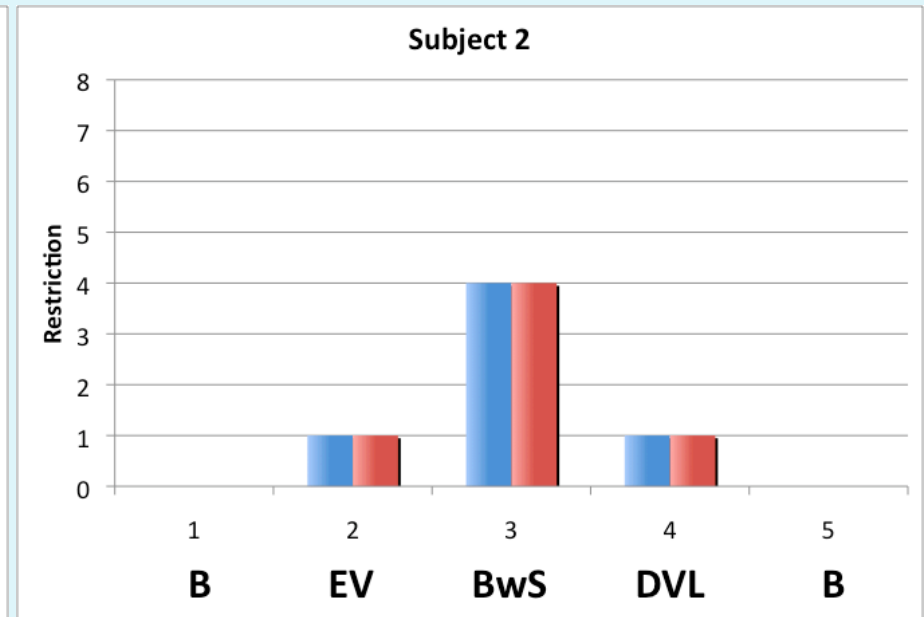
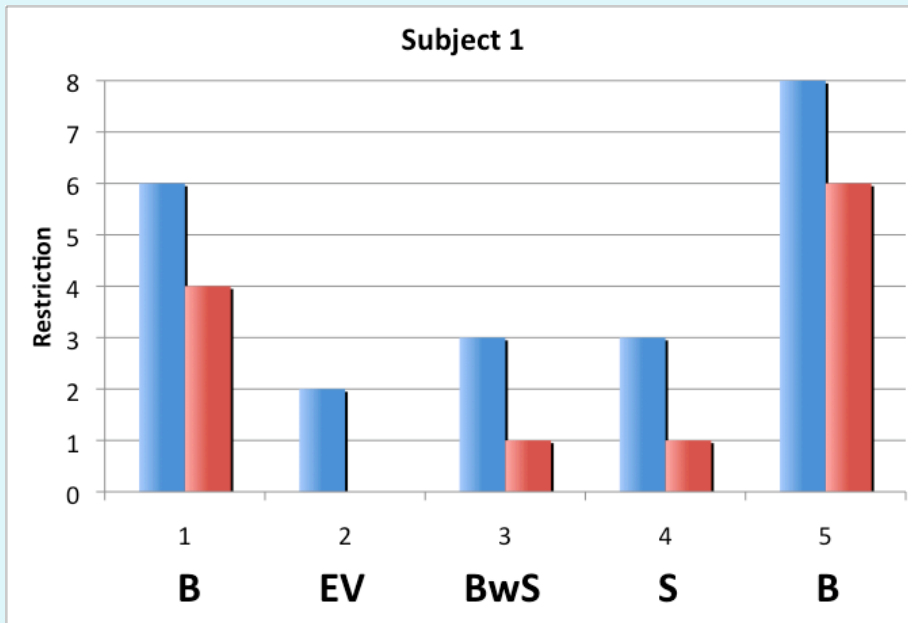
Subject 2





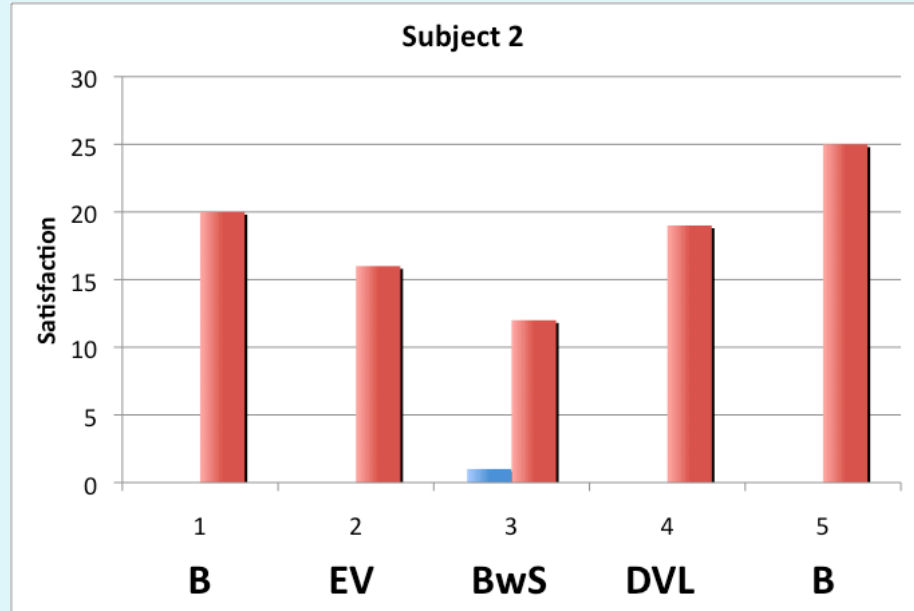
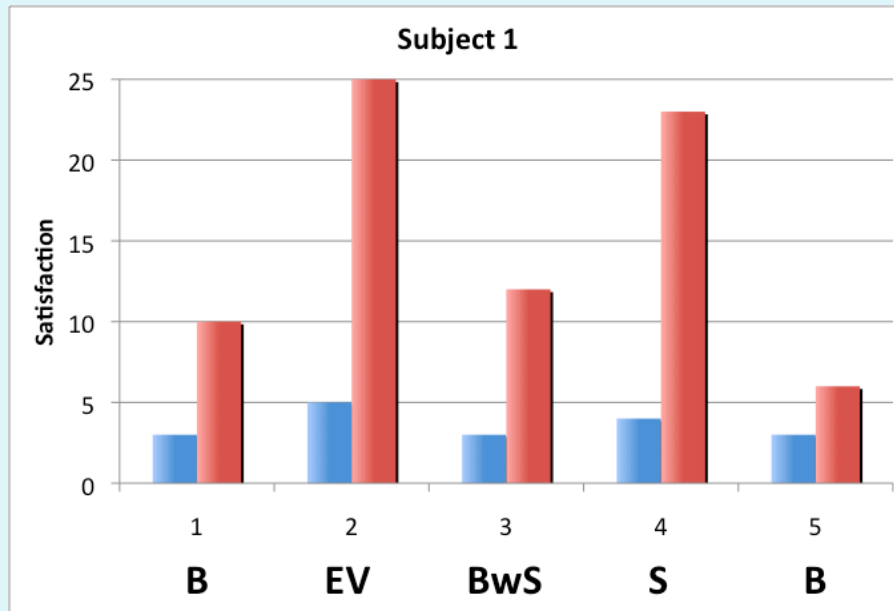
# TAPES Restriction Subscales Results

■ Athletic Activity  
■ Functional



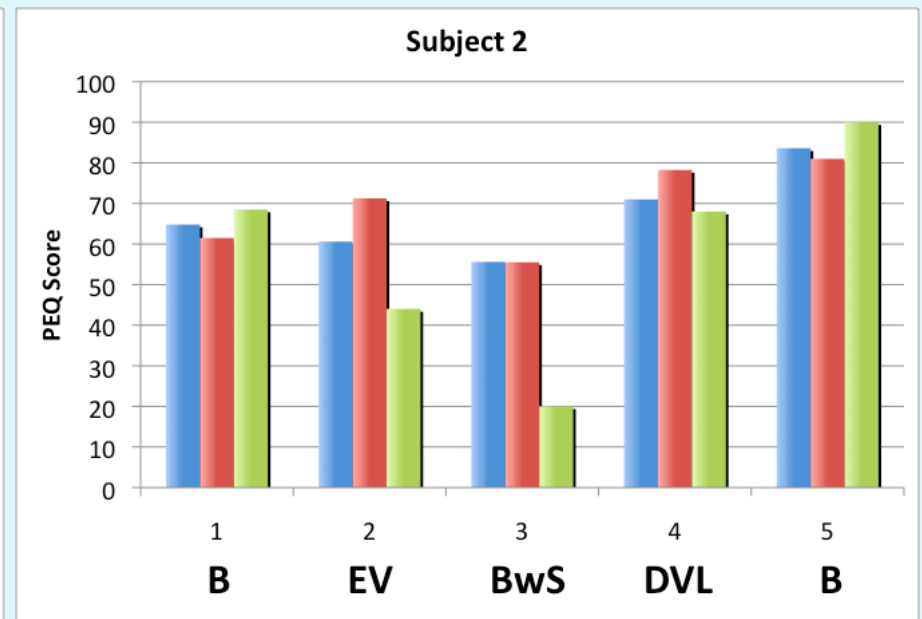
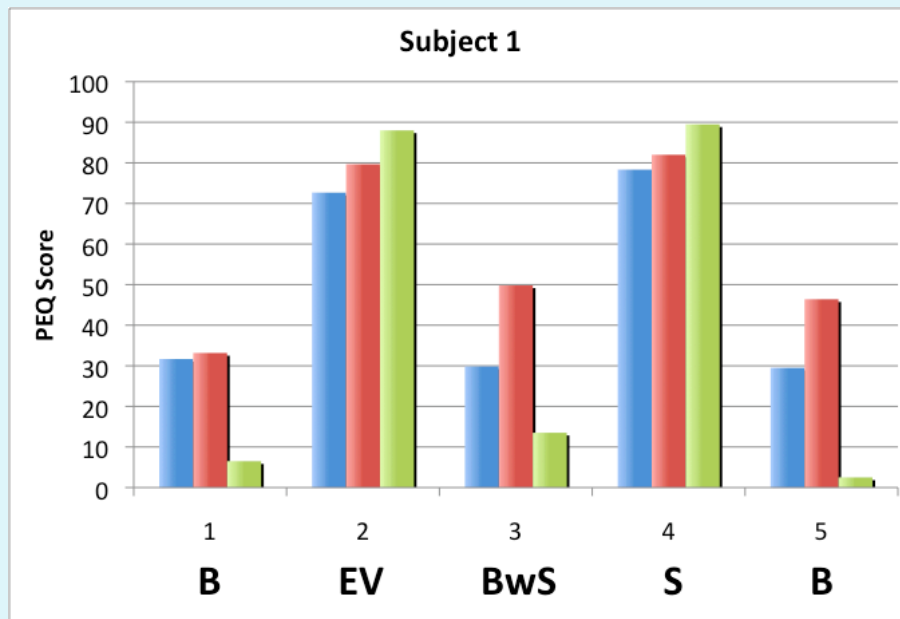
# TAPES Satisfaction Subscales Results

■ Weight  
■ Functional



# PEQ Subscale Results

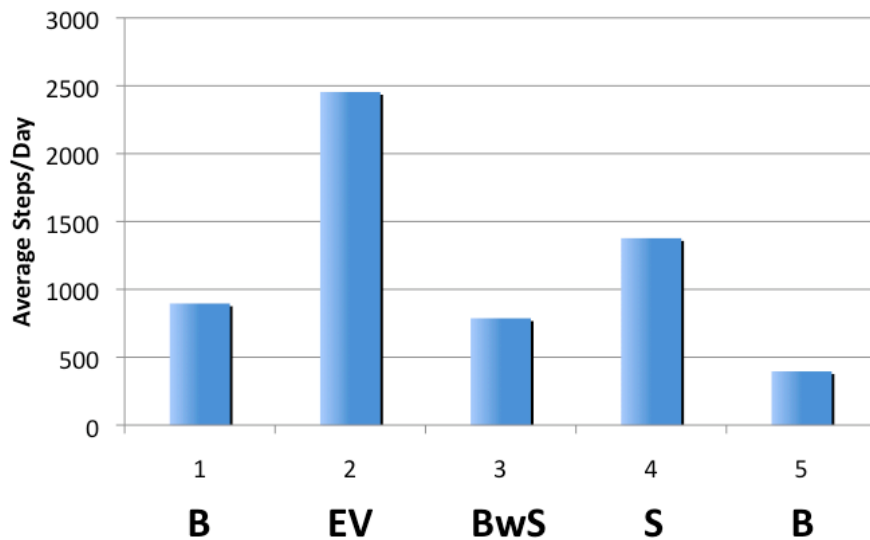
Utility  
RL Health  
Frustration



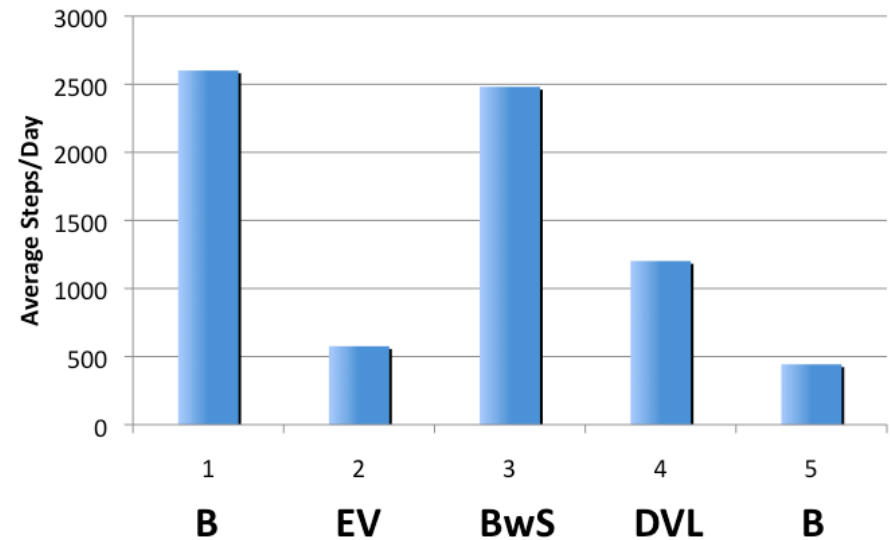
# Activity Results (Average Steps/Day)



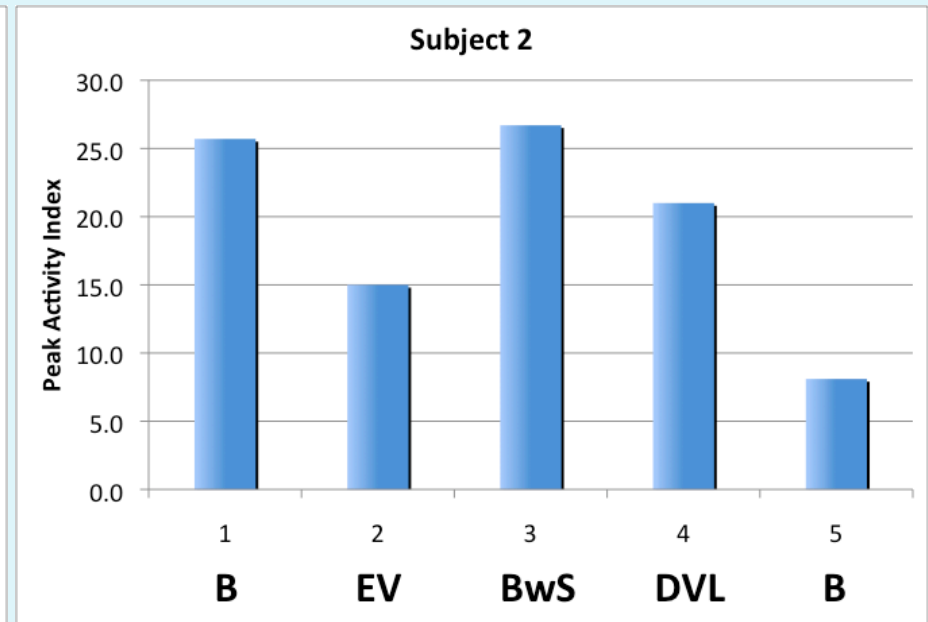
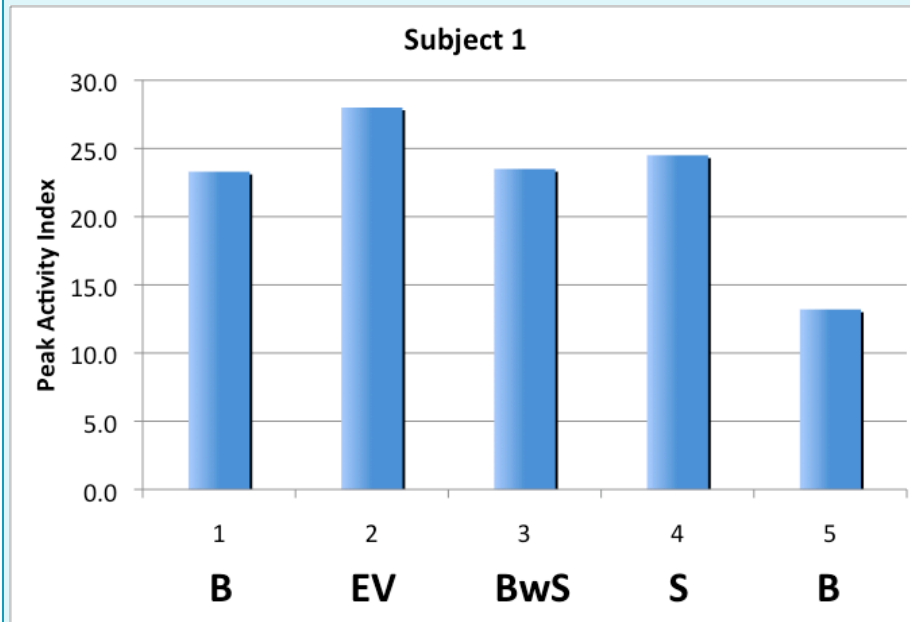
Subject 1



Subject 2



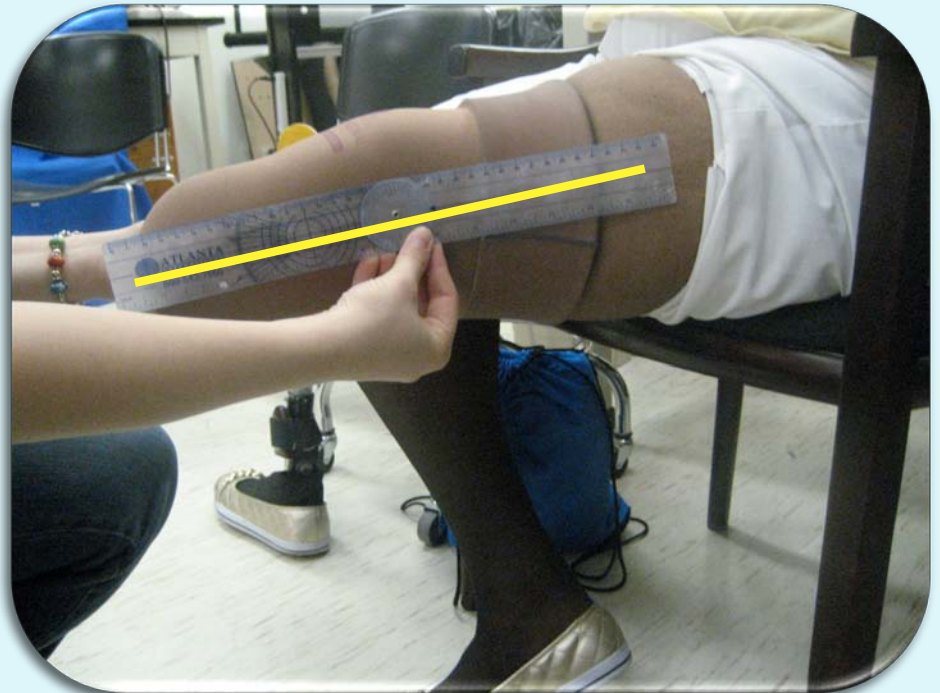
# Peak Activity Index



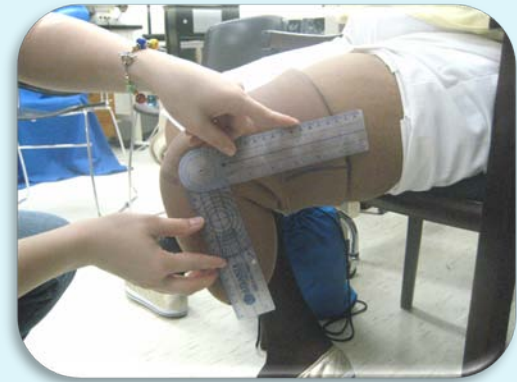
# Knee ROM



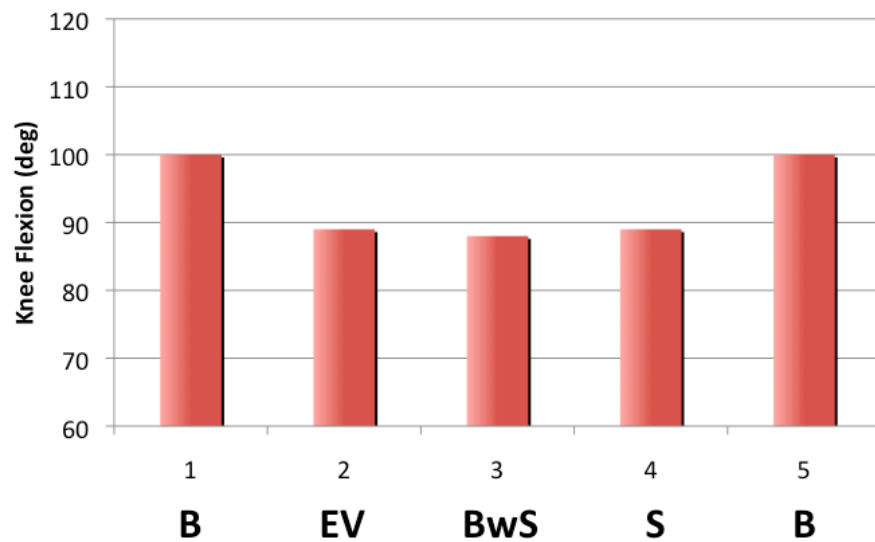
- ROM
  - Full extension =  $0^{\circ}$
  - $>$  angle =  $>$  knee flexion
  - Normal Knee ROM
    - ✦  $-5^{\circ}$  -  $140^{\circ}$  (Neumann)



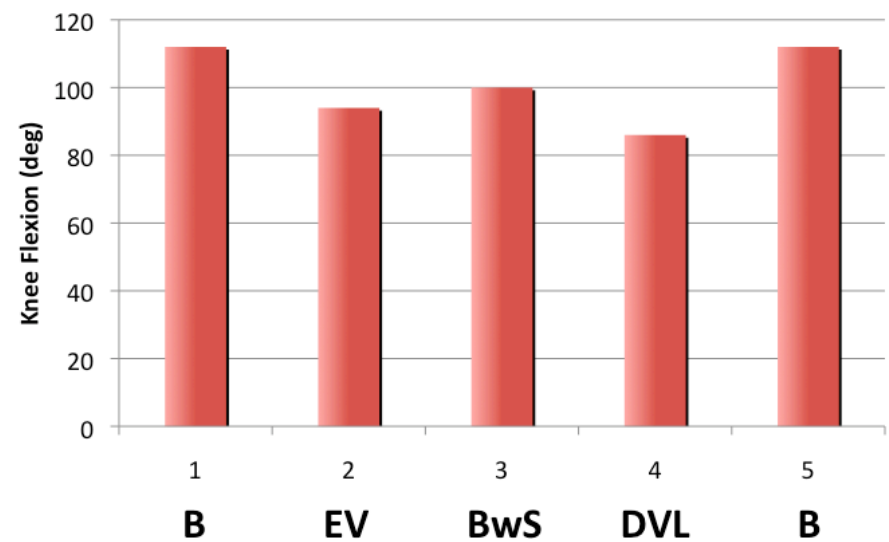
# Maximum Knee Flexion



Subject 1



Subject 2



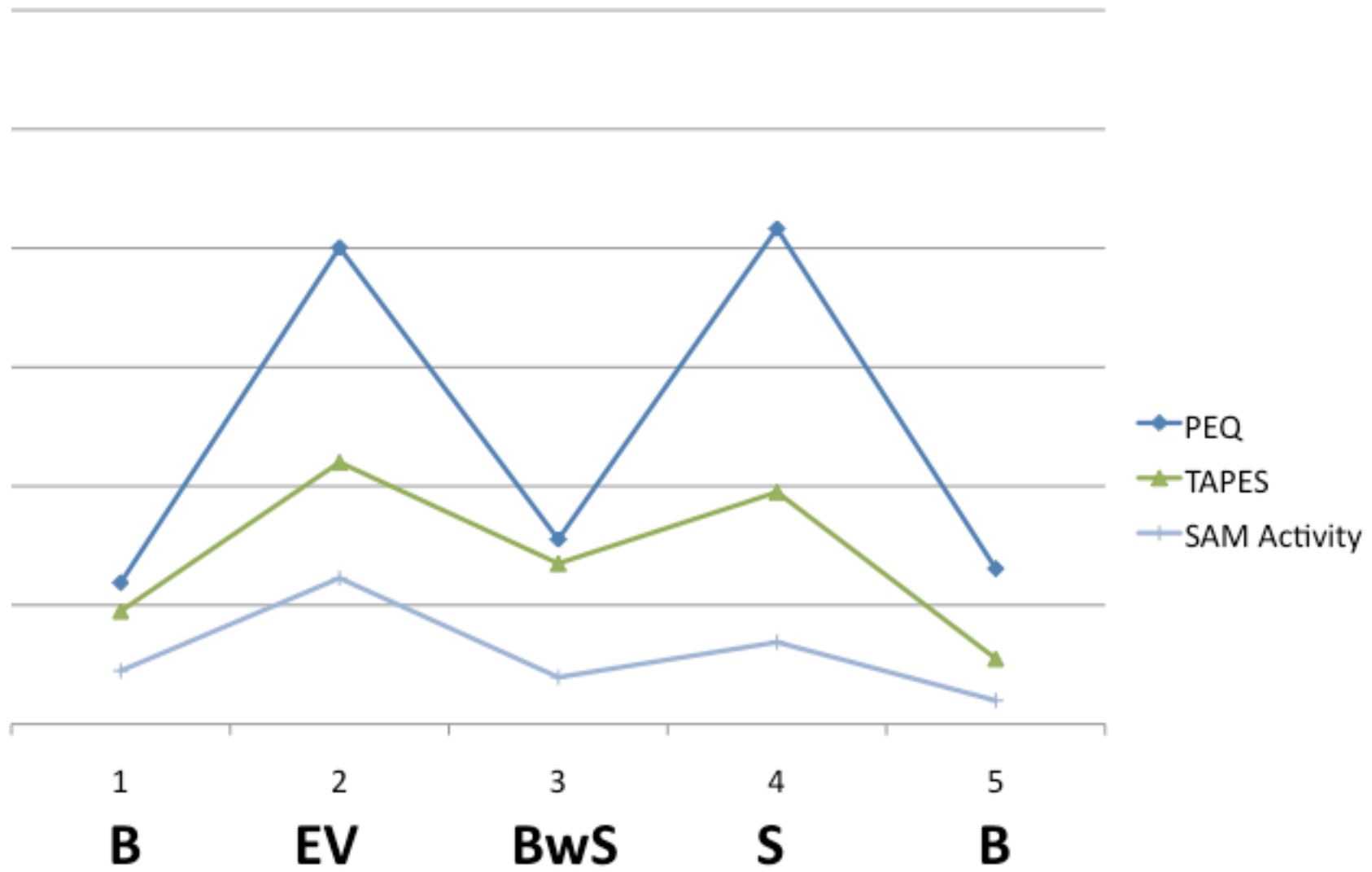
# Discussion



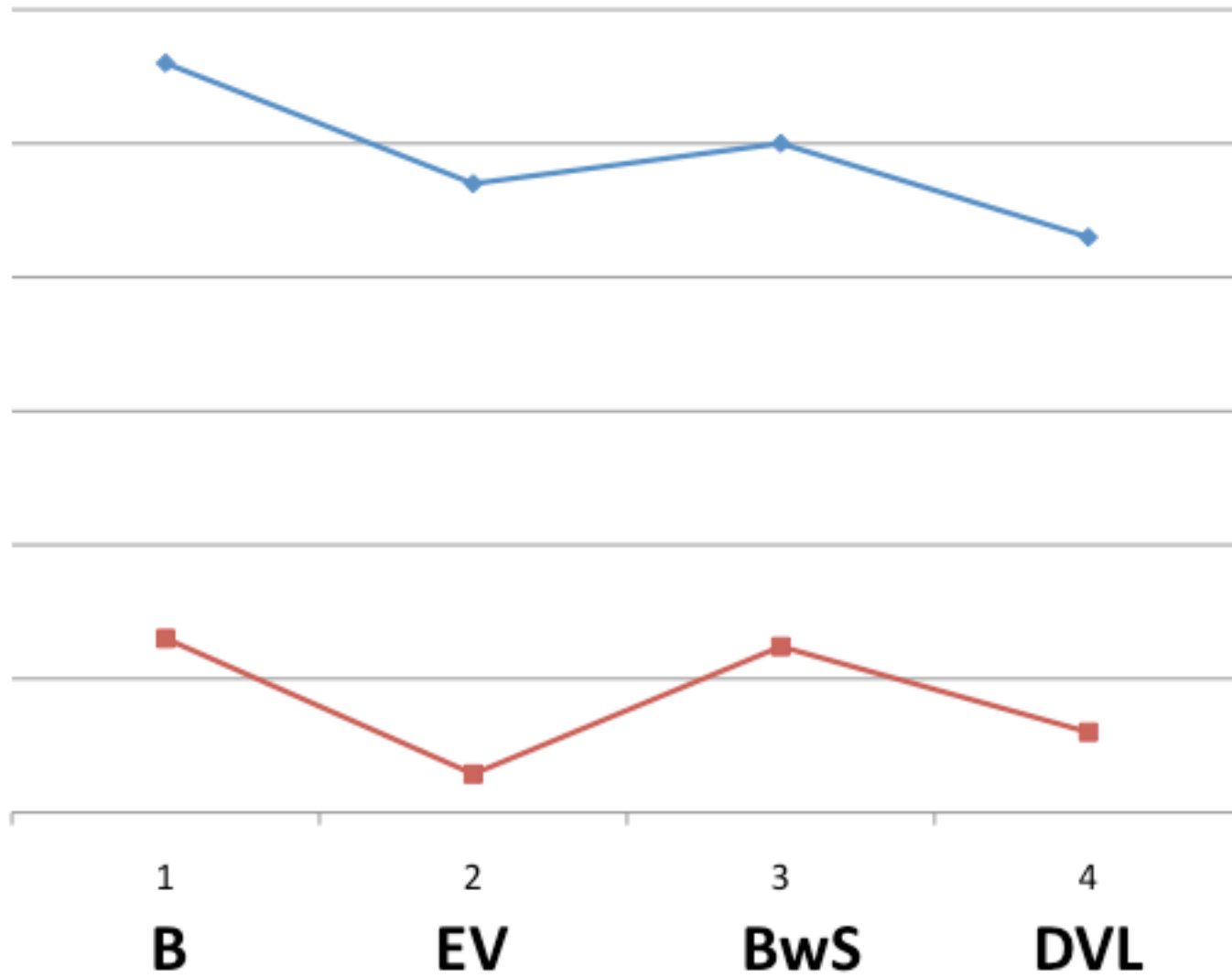
- Different subject profiles
- No statistical significance
- Patterns in the data across outcome measures



### Subject 1



Subject 2



# Discussion



- **Relation to the literature**
  - “... since all patients had a troublesome prosthetic history, the results cannot be generalized to any extent.” (Van de Weg 2005)
- **Power Analysis**

# Outcome Measures



- mEFAP
  - ✦ Designed for people with stroke
  - ✦ Individual tests used in prosthetics
  - ✦ Ceiling effect
  
- PEQ & TAPES
  - ✦ Used in literature
  - ✦ Significance not found with all subscales
  - ✦ Not all subscales are applicable
  
- SAM
  - ✦ Good indicator of activity level
  - ✦ Self-reported activity lacking

# Clinical Relevance



- Vacuum suspension may not be appropriate for all patients
  - Shape and composition of limb
  - Skin sensitivity
  - Activity level
  - Knee ROM
  - Cognitive ability
  - Hand dexterity
- Subject 3 had to withdraw

# Clinical Relevance



- Outcome measures can be performed in clinic
  - mEFAP
    - ✦ Early prosthetic wearer
  - PEQ/TAPES
    - ✦ Valuable results
  - SAM/Self-Report
    - ✦ SAM: objective & reliable
  - Knee ROM
    - ✦ Specific to pt. activity level

# Limitations



- **Subject situations**
  - Health
  - Activity level
  - Age of px.
  - Fit of px.
- **Componentry available to researchers**

# Acknowledgements



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- Ohio Willow Wood®





# References



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